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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,520	09/22/2003	Andre Stamm	107664.115 US8	5815

26694 7590 01/11/2006

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,520	STAMM ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-202* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-202* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-202 are pending in this action. Claims 1-202 are subject to an Election/Restriction requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, 55-81, 183-186, 191 and 192, drawn to a process for producing a fenofibrate composition, classified in class 424, subclass 489.

II. Claims 25-54, 82-112, 130-150, 187-190, 193-194 and 197-198, drawn to a process for producing a fenofibrate tablet, classified in class 424, subclass 464.

III. Claims 113-129 and 195-196 drawn to a process for producing a fenofibrate composition, classified in class 424, subclass 400.

IV. Claims 151-167 and 199-200, drawn to a process for producing a fenofibrate tablet, classified in class 424, subclass 465.

V. Claims 168-182 and 201-202, drawn to a process for producing a fenofibrate tablet, classified in class 424, subclass 464.

The inventions are distinct, each from the other because of the following reasons:

Each of the inventions of Group I – Group V are drawn to different processes of producing a fenofibrate composition (granulates) and fenofibrate tablet.

Group I (claims 1-24, 55-81, 183-186, 191 & 192) is drawn to a distinct process than Group II (claims 25-54, 82-112, 130-150, 187-190, 193-194 & 197-198). Group I is drawn to a process for producing a fenofibrate composition, whereby the composition is a suspension comprising a polymer and drug that is sprayed onto inert carriers, to form granulates. Group II is drawn to a process which presents compression of the granulates to form a (fenofibrate) tablet. While the Group I invention is directed to forming granulates, the Group II invention is directed to forming a drug tablet. Thus, the different processes require different process steps, resulting in different effects. Art anticipating Group I would not anticipate or render obvious Group II. The different methods require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

Group I (claims 1-24, 55-81, 183-186, 191 & 192) is drawn to a distinct process than Group III (claims 113-129 & 195-196). Group I is drawn to a process for producing a fenofibrate composition, whereby the composition is a suspension comprising a polymer and drug that is sprayed onto inert carriers, to form granulates. Group III is drawn to a process for producing a fenofibrate composition that requires preparation of an aqueous suspension comprised of a specific polymer (PVP), specific surfactant (SLS) and drug (fenofibrate) and spraying the aqueous suspension onto inert carriers. While the Group I invention is directed to forming granulates comprising a generic (hydrophilic) polymer, the Group III invention is directed to forming an aqueous suspension comprising specific ingredients (surfactant, polymer, etc.). Thus, the different processes require different process steps, resulting in different effects.

Art anticipating Group I would not anticipate or render obvious Group III. The different methods require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

Group I (claims 1-24, 55-81, 183-186, 191 & 192) is drawn to a distinct process than Group IV (claims 151-167 & 199-200). Group I is drawn to a process for producing a fenofibrate composition, whereby the composition is a suspension comprising a polymer and drug that is sprayed onto inert carriers, to form granulates. Group IV is drawn to a process for producing a fenofibrate tablet that requires specific surfactants(SLS), polymer (PVP), and drug (fenofibrate) in specifically claimed weight ratios. While the Group I invention is directed to forming granulates comprising a generic (hydrophilic) polymer, the Group IV invention is directed to the production of a fenofibrate tablet requires specifically claimed components in specifically claimed amounts. Thus, the different processes require different process steps, resulting in different effects. Art anticipating Group I would not anticipate or render obvious Group IV. The different methods require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

Group I (claims 1-24, 55-81, 183-186, 191 & 192) is drawn to a distinct process than Group V (claims 168-182 & 201-202). Group I is drawn to a process for producing a fenofibrate composition, whereby the composition is a suspension comprising a polymer and drug that is sprayed onto inert carriers, to form granulates. Group V is drawn to a process for producing a fenofibrate tablet that requires specific surfactants(SLS), polymer (PVP), and drug (fenofibrate)

in specifically claimed weight ratios. While the Group I invention is directed to forming granulates comprising a generic (hydrophilic) polymer, the Group V invention is directed to the production of a fenofibrate tablet requires specifically claimed components in specifically claimed amounts. Thus, the different processes require different process steps, resulting in different effects. Art anticipating Group I would not anticipate or render obvious Group V. The different methods require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

For similar reasons, Group II is distinct from each of Groups I and III-V.

Group II (claims 25-54, 82-112, 130-150, 187-190, 193-194 & 197-198) is drawn to a distinct process than Group I (claims 1-24, 55-81, 183-186, 191 & 192). Group II is drawn to a process which presents compression of the granulates to form a (fenofibrate) tablet. Group I is drawn to a process for producing a fenofibrate composition, whereby the composition is a suspension comprising a polymer and drug that is sprayed onto inert carriers, to form granulates. While the Group II invention is directed to forming a drug tablet, the Group I invention is directed to forming granulates. Thus, the different processes require different process steps, resulting in different effects. Art anticipating Group II would not anticipate or render obvious Group I. The different methods require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

Group II (claims 25-54, 82-112, 130-150, 187-190, 193-194 & 197-198) is drawn to a distinct process than Group III (claims 113-129 & 195-196). Group II is drawn to a process

which presents compression of the granulates to form a (fenofibrate) tablet. Group III is drawn to a process for producing a fenofibrate composition that requires preparation of an aqueous suspension comprised of a specific polymer (PVP), specific surfactant (SLS) and drug (fenofibrate) and spraying the aqueous suspension onto inert carriers. While the Group II invention is directed to forming a drug tablet, the Group III invention is directed to forming an aqueous suspension comprising specific ingredients (surfactant, polymer, etc.). Thus, the different processes require different process steps, resulting in different effects. Art anticipating Group II would not anticipate or render obvious Group III. The different methods require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

Group II (claims 25-54, 82-112, 130-150, 187-190, 193-194 & 197-198) is drawn to a distinct process than Group IV (claims 151-167 & 199-200). Group II is drawn to a process which presents compression of the granulates to form a (fenofibrate) tablet. Group IV is drawn to a process for producing a fenofibrate tablet that requires specific surfactants(SLS), polymer (PVP), and drug (fenofibrate) in specifically claimed weight ratios. While the Group II invention is directed to forming a drug tablet containing claims of generic subject matter, the Group IV invention comprises specific ingredients, such as surfactants(SLS), polymer (PVP), and drug (fenofibrate) in specifically claimed weight ratios. Thus, the different processes require different process steps, resulting in different effects. Art anticipating Group II would not anticipate or render obvious Group IV. The different methods require completely different

searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

Group II (claims 25-54, 82-112, 130-150, 187-190, 193-194 & 197-198) is drawn to a distinct process than Group V (claims 168-182 & 201-202). Group II is drawn to a process which presents compression of the granulates to form a (fenofibrate) tablet. Group V is drawn to a process for producing a fenofibrate tablet that requires specific surfactants(SLS), polymer (PVP), and drug (fenofibrate) in specifically claimed weight ratios. While the Group II invention is directed to forming a drug tablet containing claims of generic subject matter, the Group V invention comprises specific ingredients and components in specifically claimed amounts. Thus, the different processes require different process steps, resulting in different effects. Art anticipating Group II would not anticipate or render obvious Group V. The different methods require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

For similar reasons as delineated above, Group III is distinct from each of Groups I, II, IV and V.

For similar reasons as delineated above, Group IV is distinct from each of Groups I-III and V.

For similar reasons as delineated above, Group V is distinct from each of Groups I-IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-V, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Groups I and III-V, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Because the above restriction/election is complex, a telephone call to applicants to request an oral election was not made. See MPEP 812.01

Applicant is also reminded that a 1-month (not less than 30 days) shortened statutory period will be set for response when a written restriction is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N. Sheikh

Patent Examiner

Art Unit 1615

January 09, 2006

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